



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Guido KRUPP

Appln. No.: 09/937,519

371 (c) Filing Date: March 5, 2002

For: **Detection of Nucleic Acid Amplified Products**

Art Unit: 1637

Examiner: Teresa E. Strzelecka

Confirmation No.: 9641

Atty. Docket: 19006.007

Information Disclosure Statement

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the references listed on the attached Form PTO-1449.

Copies of the foreign and non-patent references listed on pages 1-3 are submitted herewith.

Copies of the U.S. patents and published applications listed on page 1 of the attached Form PTO-1449 are not submitted herewith, in accordance with the Strategic Plan Final Rule, 69 Fed. Reg 56481-56547 (September 21, 2004), effective October 21, 2004.

Further, Applicants wish to bring to the attention of the Examiner, the following co-pending applications:

1. U.S. Application No. 10/516,007
371 (c) Filing Date: June 8, 2005
Entitled: Amplification of Ribonucleic Acids;

2. U.S. Application No. 10/526,487
Int'l Filing Date: September 3, 2003
Entitled: Improved Methods for the Synthesis of Nucleic Acids; and
3. U.S. Application No. 60/712,820
Filed: September 1, 2005
Entitled: Universal Method for Selective Amplification of mRNAs

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Certification and/or Fee

Because this Information Disclosure Statement is being submitted after issuance of the first action on the merits of the above-captioned application, a fee of \$180.00 is due pursuant to 37 C.F.R. § 1.17(p). Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

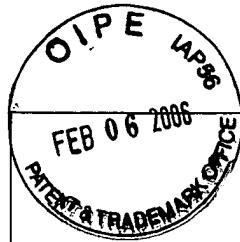
Respectfully submitted,



David R. Marsh (Reg. No. 41,408)
Rachel L. Adams (Reg. No. 54,660)

Date: February 6, 2006

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FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

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| ATTY. DOCKET NO. | APPLICATION NO. |
| 19006.007 | 09/937,519 |
| APPLICANTS | |
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U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | REFERENCE PROVIDED* |
|------------------|-----|--------------------|------------|--------------------------|--------------------------------------|
| | AA1 | 4,683,195 | 07/28/1987 | Mullis <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AB1 | 4,683,202 | 07/28/1987 | Mullis | not required, per 69 Fed. Reg. 56481 |
| | AC1 | 5,130,238 | 07/14/1992 | Malek <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AD1 | 5,256,555 | 10/26/1993 | Milburn <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AE1 | 5,262,311 | 11/16/1993 | Pardee <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AF1 | 5,407,800 | 04/18/1995 | Gelfand <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AG1 | 5,459,037 | 10/17/1995 | Sutcliffe <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AH1 | 5,514,545 | 05/07/1996 | Eberwine | not required, per 69 Fed. Reg. 56481 |
| | AI1 | 5,545,522 | 08/13/1996 | Van Gelder <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AJ1 | 5,561,058 | 10/01/1996 | Gelfand <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AK1 | 5,599,672 | 02/04/1997 | Liang | not required, per 69 Fed. Reg. 56481 |
| | AL1 | 5,665,547 | 09/09/1997 | Pardee <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AM1 | 5,716,785 | 02/10/1998 | Van Gelder <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AN1 | 5,780,273 | 07/14/1998 | Burg | not required, per 69 Fed. Reg. 56481 |
| | AO1 | 5,837,501 | 11/17/1998 | Beumer <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AP1 | 5,891,636 | 04/06/1999 | Van Gelder <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AQ1 | 5,932,451 | 08/03/1999 | Wang <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AR1 | 5,958,688 | 09/28/1999 | Eberwine <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AS1 | 5,965,409 | 10/12/1999 | Pardee <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AT1 | 5,972,607 | 10/26/1999 | Kondo <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AU1 | 6,090,589 | 07/18/2000 | Dimond <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AV1 | 6,132,997 | 10/17/2000 | Shannon | not required, per 69 Fed. Reg. 56481 |
| | AW1 | 6,291,170 B1 | 09/18/2001 | Van Gelder <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AX1 | US 6,361,949 B1 | 03/26/2002 | Sommer | not required, per 69 Fed. Reg. 56481 |
| | AY1 | US 6,379,932 B1 | 04/30/2002 | Arnold <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | AZ1 | US 2003/0129624 A1 | 07/10/2003 | Eastman <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |
| | BA1 | US 2005/0009027 A1 | 01/13/2005 | Krupp <i>et al.</i> | not required, per 69 Fed. Reg. 56481 |

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FOREIGN PATENT DOCUMENTS

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|------------------|-----|-----------------|------------|--|---------------------|-----------------------------|
| | AA2 | 0 201 184 A2 | 12/17/1986 | EPO | submitted herewith | Yes No |
| | AB2 | 0 329 822 A2 | 08/26/1989 | EPO | submitted herewith | Yes No |
| | AC2 | 0 329 822 A3 | 08/01/1990 | EPO | submitted herewith | Yes No |
| | AD2 | 0 329 822 B1 | 06/08/1994 | EPO | submitted herewith | Yes No |
| . | AE2 | 0 416 572 B1 | 05/17/1995 | EPO | submitted herewith | (claims only) X Yes No |
| | AF2 | 0 525 882 A1 | 02/03/1993 | EPO | submitted herewith | Yes No |
| | AG2 | EP 0 525 882 B1 | 01/14/2004 | EPO | submitted herewith | Yes No |
| | AH2 | EP 0 592 626 B1 | 01/29/2003 | EPO | submitted herewith | Yes No |
| | AI2 | EP 0 707 076 A1 | 04/17/1996 | EPO | submitted herewith | Yes No |
| | AJ2 | EP 0 707 076 B1 | 03/27/2002 | EPO | submitted herewith | Yes No |
| | AK2 | EP 1 275 734 A1 | 01/15/2003 | EPO | submitted herewith | Yes No |
| | AL2 | JP 08/205897 A | 08/13/1996 | Japan | submitted herewith | (abstract only) X Yes No |
| | AM2 | JP 2843675 B2 | 01/06/1999 | Japan; nat'l phase of WO 93/18176 A1, submitted herewith | submitted herewith | X Yes No |
| | AN2 | WO 90/14439 A1 | 11/29/1990 | PCT | submitted herewith | Yes No |
| | AO2 | WO 92/08800 A1 | 05/29/1992 | PCT | submitted herewith | Yes No |
| | AP2 | WO 93/18176 A1 | 09/16/1993 | PCT | submitted herewith | Yes No |
| | AQ2 | WO 94/13833 A1 | 06/23/1994 | PCT | submitted herewith | Yes No |
| | AR2 | WO 99/47704 A1 | 09/23/1999 | PCT | submitted herewith | (abstract only) X Yes No |
| | AS2 | WO 00/18966 A2 | 04/06/2000 | PCT | submitted herewith | Yes No |
| | AT2 | WO 00/18966 A3 | 07/27/2000 | PCT | submitted herewith | Yes No |

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|------------------|-----|-------------------|------------|---------|---------------------|--|
| | AA3 | WO 00/75356 A1 | 12/14/2000 | PCT | submitted herewith | Yes No |
| | AB3 | WO 01/71036 A2 | 09/27/2001 | PCT | submitted herewith | Yes No |
| | AC3 | WO 01/071036 A3 | 10/24/2002 | PCT | submitted herewith | Yes No |
| | AD3 | WO 03/020873 A2 | 03/13/2003 | PCT | submitted herewith | (abstract <input checked="" type="checkbox"/> Yes only) <input type="checkbox"/> No |
| | AE3 | WO 03/102232 A2 | 12/11/2003 | PCT | submitted herewith | (abstract <input checked="" type="checkbox"/> Yes only) <input type="checkbox"/> No |
| | AF3 | WO 2004/022574 A2 | 03/18/2004 | PCT | submitted herewith | (abstract <input checked="" type="checkbox"/> Yes only) <input type="checkbox"/> No |

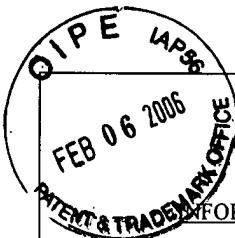
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AG3 | Baugh <i>et al.</i> , "Quantitative analysis of mRNA amplification by <i>in vitro</i> transcription", <i>Nucleic Acids Research</i> , 29(5):1-9 (2001) | submitted herewith |
| | AH3 | Berger <i>et al.</i> , "Reverse Transcriptase and Its Associated Ribonuclease H: Interplay of Two Enzyme Activities Controls the Yield of Single-Stranded Complementary Deoxyribonucleic Acid", <i>Biochemistry</i> , 22(10):2365-2372 (1983) | submitted herewith |
| | AI3 | Boom <i>et al.</i> , "Rapid and Simple Method for Purification of Nucleic Acids", <i>J. Clin. Microbiol.</i> , 28(3):495-503 (1990) | submitted herewith |
| | AJ3 | Boularand <i>et al.</i> , "The Human Tryptophan Hydroxylase Gene: an Unusual Splicing Complexity in the 5'-Untranslated Region", <i>J. Biol. Chem.</i> , 270(8):3748-3756 (1995) | submitted herewith |
| | AK3 | Bratty <i>et al.</i> , "The hammerhead RNA domain, a model ribozyme", <i>Biochim. Biophys. Acta</i> , 1216:345-359 (1993) | submitted herewith |
| | AL3 | Burgin <i>et al.</i> , "Chemically Modified Hammerhead Ribozymes with Improved Catalytic Rates", <i>Biochemistry</i> , 35(45):14090-14097 (1996) | submitted herewith |
| | AM3 | Clouet-d'Orval <i>et al.</i> , "Hammerhead Ribozymes with a Faster Cleavage Rate", <i>Biochemistry</i> , 36(30):9087-9092 (1997) | submitted herewith |
| | AN3 | Database WPI, AN 96-419828, Abstract of JP 8-205897, Derwent Publications Ltd. (October 1996) | submitted herewith |

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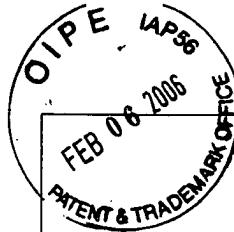
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| AA4 | Eberwine <i>et al.</i> , "Analysis of gene expression in single live neurons", <i>Proc. Natl. Acad. Sci. USA</i> , 89:3010-3014 (1992) | submitted herewith |
| AB4 | Fahy <i>et al.</i> , "Self-sustained Sequence Replication (3SR): An Isothermal Transcription-based Amplification System Alternative to PCR", <i>PCR Methods and Applications</i> , 1:25-33 (1991) | submitted herewith |
| AC4 | Feinberg <i>et al.</i> , "A Technique for Radiolabeling DNA Restriction Endonuclease Fragments to High Specific Activity", <i>Analytical Biochemistry</i> , 132(1):6-13 (1983) | submitted herewith |
| AD4 | Frohman <i>et al.</i> , "Rapid production of full-length cDNAs from rare transcripts: Amplification using a single gene-specific oligonucleotide primer", <i>Proc. Natl. Acad. Sci. USA</i> , 85:8998-9002 (1988) | submitted herewith |
| AE4 | Hames <i>et al.</i> (Eds.), <u>Nucleic acid hybridisation: a practical approach</u> (Practical Approach Series), IRL Press Ltd., pp. 179-202 (1985) | submitted herewith |
| AF4 | Hanne <i>et al.</i> , "Fluorescence resonance energy transfer (FRET) to follow ribozyme reactions in real time", <i>Nucleosides & Nucleotides</i> , 17(9-11):1835-1850 (1998) | submitted herewith |
| AG4 | International Search Report, Application No. PCT/EP99/07127 (April 7, 2000) | submitted herewith |
| AH4 | International Search Report, Application No. PCT/EP02/09348 (August 22, 2003) | submitted herewith |
| AI4 | International Search Report, Application No. PCT/EP03/05579 (December 12, 2003) | submitted herewith |
| AJ4 | International Search Report, Application No. PCT/EP03/09756 (March 4, 2004) | submitted herewith |
| AK4 | Jenne <i>et al.</i> , "Real-Time Characterization of Ribozymes by Fluorescence Resonance Energy Transfer (FRET)", <i>Angew. Chem. Int. Ed.</i> , 38(9):1300-1303 (1999) | submitted herewith |
| AL4 | Kievits <i>et al.</i> , "NASBA™ isothermal enzymatic in vitro nucleic acid amplification optimized for the diagnosis of HIV-1 infection", <i>J. Virol. Methods</i> , 35(3):273-286 (1991) | submitted herewith |

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| | | |
|-----|---|--------------------|
| AA5 | Konarska <i>et al.</i> , "Replication of RNA by the DNA-Dependent RNA Polymerase of Phage T7", <i>Cell</i> , 57:423-431 (1989) | submitted herewith |
| AB5 | Konarska <i>et al.</i> , "Structure of RNAs Replicated by the DNA-Dependent T7 RNA Polymerase", <i>Cell</i> , 63:609-618 (1990) | submitted herewith |
| AC5 | Krupp, "Stringent RNA quality control using the Agilent 2100 bioanalyzer", Application Note, Agilent Technologies (2005) | submitted herewith |
| AD5 | Krupp, "Unusual promoter-independent transcription reactions with bacteriophage RNA polymerases", <i>Nucleic Acids Research</i> , 17(8):3023-3036 (1989) | submitted herewith |
| AE5 | Kuhn <i>et al.</i> , "Specific interaction of the murine transcription termination factor TTF I with class-I RNA polymerases", <i>Nature</i> , 344:559-562 (1990) | submitted herewith |
| AF5 | Liang <i>et al.</i> , "Differential Display of Eukaryotic Messenger RNA by Means of the Polymerase Chain Reaction", <i>Science</i> , 257:967-971 (1992) | submitted herewith |
| AG5 | Lockhart <i>et al.</i> , "Expression monitoring by hybridization to high-density oligonucleotide arrays", <i>Nature Biotechnology</i> , 14:1675-1680 (1996) | submitted herewith |
| AH5 | Löffler <i>et al.</i> , <u>Biochemie und Pathobiochemie</u> , pp. 150-154, Springer-Verlag (1998) | submitted herewith |
| AI5 | Mahony <i>et al.</i> , "Urine Specimens from Pregnant and Nonpregnant Women Inhibitory to Amplification of <i>Chlamydia trachomatis</i> Nucleic Acid by PCR, Ligase Chain Reaction, and Transcription-Mediated Amplification: Identification of Urinary Substances Associated with Inhibition and Removal of Inhibitory Activity", <i>J. Clin. Microbiol.</i> , 36(11):3122-3126 (1998) | submitted herewith |
| AJ5 | Mathieu-Daudé <i>et al.</i> , "DNA rehybridization during PCR: the 'C _t effect' and its consequences", <i>Nucleic Acids Research</i> , 24(11):2080-2086 (1996) | submitted herewith |
| AK5 | Milligan <i>et al.</i> , "Synthesis of Small RNAs Using T7 RNA Polymerase", <u>Methods in Enzymology</u> , Vol. 180, pp. 51-62, Academic Press, Inc. (1989) | submitted herewith |
| AL5 | Mueller <i>et al.</i> , "RNA Integrity Number (RIN) - Standardization of RNA Quality Control", Application Note, Agilent Technologies (2004) | submitted herewith |

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| | | |
|-----|--|--------------------|
| AA6 | Müller <i>et al.</i> , "Amino Acid Requirements of the Nucleocapsid Protein of HIV-1 for Increasing Catalytic Activity of a Ki-ras Ribozyme", <i>J. Mol. Biol.</i> , 242:422-429 (1994) | submitted herewith |
| AB6 | Nedbal <i>et al.</i> , "The Association of Complementary Ribonucleic Acids Can Be Strongly Increased without Lowering Arrhenius Activation Energies or Significantly Altering Structures", <i>Biochemistry</i> , 36:13552-13557 (1997) | submitted herewith |
| AC6 | Pezo <i>et al.</i> , "Hypermutagenic in vitro transcription employing biased NTP pools and manganese cations", <i>Gene</i> , 186:67-72 (1997) | submitted herewith |
| AD6 | Poirier <i>et al.</i> , "Screening differentially expressed cDNA clones obtained by differential display using amplified RNA", <i>Nucleic Acids Research</i> , 25(4):913-914 (1997) | submitted herewith |
| AE6 | Puskás <i>et al.</i> , "RNA Amplification Results in Reproducible Microarray Data with Slight Ratio Bias", <i>BioTechniques</i> , 32(6):1330-1340 (2002) | submitted herewith |
| AF6 | Richmond <i>et al.</i> , "Genome-wide expression profiling in <i>Escherichia coli</i> K-12", <i>Nucleic Acids Research</i> , 27(19):3821-3835 (1999) | submitted herewith |
| AG6 | Saiki <i>et al.</i> , "Enzymatic Amplification of β-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia", <i>Science</i> , 230:1350-1354 (1985) | submitted herewith |
| AH6 | Sargent, "Isolation of Differentially Expressed Genes", <i>Methods in Enzymology</i> , Vol. 152, pp. 423-432, Academic Press, Inc. (1987) | submitted herewith |
| AI6 | Sarkar <i>et al.</i> , "Access to a Messenger RNA Sequence or its Protein Product is Not Limited by Tissue or Species Specificity", <i>Science</i> , 244:331-334 (1989) | submitted herewith |
| AJ6 | Singh <i>et al.</i> , "Design of Hammerhead Ribozymes to Distinguish Single Base Changes in Substrate RNA", <i>Antisense and Nucleic Acid Drug Development</i> , 6:165-168 (1996) | submitted herewith |
| AK6 | Sioud <i>et al.</i> , "Enhancement of Hammerhead Ribozyme Catalysis by Glyceraldehyde-3-phosphate Dehydrogenase", <i>J. Mol. Biol.</i> , 257:775-789 (1996) | submitted herewith |
| AL6 | Sooknanan <i>et al.</i> , "Nucleic Acid Sequence-Based Amplification", <i>Molecular Methods for Virus Detection</i> , Wiedbrauk and Farkas (eds.), Chapter 12, pp 261-285, Academic Press, Inc. (1995) | submitted herewith |

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| AA7 | Stoflet <i>et al.</i> , "Genomic Amplification with Transcript Sequencing", <i>Science</i> , 239:491-494 (1988) | | submitted herewith |
| AB7 | Taylor <i>et al.</i> , "Chimeric DNA-RNA hammerhead ribozymes have enhanced <i>in vitro</i> catalytic efficiency and increased stability <i>in vivo</i> ", <i>Nucleic Acids Research</i> , 20(17):4559-4565 (1992) | | submitted herewith |
| AC7 | Tyagi <i>et al.</i> , "Multicolor molecular beacons for allele discrimination", <i>Nature Biotechnology</i> , 16:49-53 (1998) | | submitted herewith |
| AD7 | Van Gelder <i>et al.</i> , "Amplified RNA synthesised from limited quantities of heterogeneous cDNA", <i>Proc. Natl. Acad. Sci. USA</i> , 87:1663-1667 (1990) | | submitted herewith |
| AE7 | Wyatt <i>et al.</i> , "Synthesis and Purification of Large Amounts of RNA Oligonucleotides", <i>BioTechniques</i> , 11(6):764-769 (1991) | | submitted herewith |
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*Copies of the listed references are either submitted herewith or were previously cited by or submitted to, the Office in a prior application. Pursuant to 37 C.F.R. § 1.97(d) and MPEP §609, the indicated reference may have been previously cited by or submitted to, the Office in a prior application, where the prior application is identified by its U.S. Application Number in this Information Disclosure Statement.